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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/625,825 | 07/22/2003 | Anatoly E. Martynyuk | UF-281D2 | 7782 |

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| EXAMINER | |
|---|---|
| SPIVACK, PHYLLIS G | |
| **ART UNIT** | **PAPER NUMBER** |
| 1614 | |

DATE MAILED: 08/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| **Advisory Action Before the Filing of an Appeal Brief** | **Application No.** 10/625,825 | **Applicant(s)** MARTYNYUK ET AL. | |
|---|---|---|---|
| | **Examiner** Phyllis G. Spivack | **Art Unit** 1614 | |

***--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***

THE REPLY FILED 21 June 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: *10,11 and 13*.
   Claim(s) rejected: *1-9*.
   Claim(s) withdrawn from consideration: *14-34*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☒ Other: See Continuation Sheet.

Phyllis Spivack

Phyllis G. Spivack
Primary Examiner
Art Unit: 1614

PHYLLIS SPIVACK
PRIMARY EXAMINER

Continuation of 5. Applicant's reply has overcome the following rejection(s): the rejection of claims 9, 11, 13 under 35 U.S.C. 112, second paragraph; the rejection of claims 6, 7, 10, 11 and 13 under 35 U.S.C. 103 as being unpatentable over Liechty et al., Journal of Nutrition; the rejection of claims 4, 5, 10, 11 and 13 under 35 U.S.C. 102(b) as being anticipated by Liechty et al., Journal of Nutrition; the rejection of claims 9-11 and 13 under 35 U.S.C. 102(b) as being anticipated by The Merck Index.

Continuation of 13. Other: The rejection of record directed to provisional obviousness-type double patenting is maintained.
The rejection of claims 6 and 7 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because claims 6 and 7 are drawn to functional characteristics, rather than structural characteristics, of the components of the claimed "article of manufacture", is maintained. The specification fails to define the actual compounds contemplated that are "facilitating substances" in the present composition claims. Applicants' argument drawn to the name "facilitating substances" based on functional properties is not persuasive. A definition of a "facilitating substance" based on to what certain compounds in the claimed pharmaceutical composition do, instead of what they actually are, does not enable the skilled practitioner to prepare an article of manufacture without undue experimentation.

The rejection of claims 1-5, 8 and 9 under 35 U.S.C. 103 as being unpatentable over Liechty et al., Journal of Nutrition, is maintained. The replacement of the term "comprising" with the recitation "consisting essentially of" is noted; however, Applicants argue the concentration of many non-aromatic amino acids, specifically large neutral amino acids, would be "interfering substances." Such an assertion must be considered without merit since Applicants' invention is drawn solely to the administration of at least one aromatic amino acid, an isomer or analog thereof, to treat neurological disorders specifically involving glutamatergic synaptic transmission. It would have been reasonable to conclude the presence of other amino acids would have no effect on glutamatergic synaptic transmission.

The rejection of claims 1, 2, 8 and 9 under 35 U.S.C. 102(b), as being anticipated by Liechty et al., Journal of Nutrition, is maintained. See column one, page 1162, under Materials and Methods, where infusions of both L-phenylalanine and L-tyrosine are admininstered. Further, a priming dose was given as a bolus. As required by claim 9, both L-phenylalanine and L-tyrosine were admixed as a bolus.

The rejection of claims 1 and 8 under 35 U.S.C. 102(b), as being anticipated by The Merck Index, is maintained. Page 1253 discloses L-phenylalanine as a component of a known commercial product, an artificial sweeter, that is formulated with a carrier.